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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,993	11/04/2003	Charles R. Saikley	THER.011US1	6633

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EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/701,993	<b>Applicant(s)</b> SAIKLEY ET AL.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 and 10 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement(s) (IDS) submitted on 07/12/2004, 09/10/2004, 03/07/2005, and 08/12/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

### ***Specification***

2. The abstract of the disclosure is objected to because of legalese (e.g. use of "comprises"). Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (US 5,279,294).
5. For claim 21, Anderson et al discloses a device for obtaining and testing a sample, comprising: a housing 16,18, and a lancing device 14 operatively coupled to said housing for obtaining a sample; wherein the housing is of a construction sufficient to receive a test strip 12 for substantially capturing at least a portion of the sample and for providing a result that corresponds to the captured portion of the sample via display 24.

Art Unit: 3736

6. For claim 22, Anderson et al discloses the device of claim 21, wherein the lancing device 14 comprises a cutting edge that is substantially aligned with the test strip 12 when the test strip is received in the housing as best seen in Figures 4, 13, 14f, 14g, and 14h.

7. For claim 23, Anderson et al discloses the device of claim 21, wherein the lancing device is operatively coupled to said housing by a spring mechanism 68.

8. For claim 24, Anderson et al discloses the device of claim 21, wherein the lancing device comprises a body having a first axis, and a sharp operatively connected to the body, wherein the sharp has a second axis that is substantially perpendicular to the first axis as best seen in Figures 14d and 14i.

9. For claim 26, Anderson et al discloses the device of claim 21, wherein the lancing device is of a construction sufficient to pierce tissue of a patient (column 3 lines 40-42).

10. For claim 27, Anderson et al discloses the device of claim 21, wherein when the test strip is received in the housing, the test strip is movable from a received position to a sample-contacting position, via a user as best seen in Figure 13.

11. For claim 28, Anderson et al discloses the device of claim 27, wherein when the test strip is in the sample-contacting position, a fill channel 70 of the test strip is substantially aligned with the sample.

12. For claim 29, Anderson et al discloses the device of claim 21, wherein the result corresponds to a physiological property of the captured portion of the sample (column 2 line 64 – column 3 line 1 and column 4 lines 24-30).

Art Unit: 3736

13. For claim 30, Anderson et al discloses the device of claim 29, wherein the physiological property of the captured portion of the sample is a glucose level, a carbohydrate level, a hemoglobin level, or a glycated hemoglobin level (column 4 lines 24-30).

14. For claim 31, Anderson et al discloses the device of claim 21, further comprising a controller 130 operatively coupled to the housing for controlling operation of the lancing device

15. For claim 32, Anderson et al discloses the device of claim 21, further comprising an input unit 30 operatively coupled to the housing for operating the lancing device.

16. For claim 33, Anderson et al discloses the device of claim 21, further comprising a controller, a hand as best seen in Figure 13, operatively coupled to the housing for controlling movement of the test strip when the test strip is received in the housing.

17. For claim 34, Anderson et al discloses the device of claim 21, further comprising a display 24 operatively coupled to the housing for displaying the result.

18. For claim 35, Anderson et al discloses the device of claim 34, further comprising a controller 116 operatively coupled to the housing for controlling the display.

19. For claim 36, Anderson et al discloses a device for obtaining and testing a sample constituting structure inherently capable of performing a method for obtaining and testing a sample from a patient, comprising: providing an automated device 10 on a test site of a patient, the automated device of a construction sufficient to obtain a sample from the test site, to test the sample for an analyte, and to provide a result of the

Art Unit: 3736

test, automatically upon activation; and activating the device (column 2 line 39 – column 5 line 9).

20. For claim 38, Anderson et al discloses a device for obtaining and testing a sample constituting structure inherently capable of performing a method for obtaining and testing a sample from a patient, comprising: the method of claim 36, wherein the automated device is of a construction sufficient to pierce the test site and to move a test strip into contact with the sample from the pierced test site, automatically upon activation (column 2 line 39 – column 5 line 9).

21. For claim 39, Anderson et al discloses a device for obtaining and testing a sample constituting structure inherently capable of performing a method for obtaining and testing a sample from a patient, comprising: activating an automated device, the automated device of a construction sufficient to obtain a sample, to test the sample for an analyte, and to provide a result of the test, upon activation (column 2 line 39 – column 5 line 9).

22. For claim 40, Anderson et al discloses a device for obtaining and testing a sample constituting structure inherently capable of performing a method for obtaining and testing a sample from a patient, comprising: the method of claim 39, wherein the sample is blood (column 2 line 39 – column 5 line 9).

23. For claim 41, Anderson et al discloses a device for obtaining and testing a sample constituting structure inherently capable of performing a method for obtaining and testing a sample from a patient, comprising: the method of claim 39, wherein the analyte is glucose (column 2 line 39 – column 5 line 9).

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in view of Yuzhakov et al (US 2003/0028125 A1). Anderson et al discloses the claimed invention except for the lancing device comprising a sharp with at least two points. Yuzhakov et al teaches a device for obtaining and testing a sample comprising a plurality of sharp points as best seen in Figures 3a and 3b. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sample obtaining and testing device as taught by Anderson et al, with Yuzhakov et al for the purpose of piercing the skin of a test subject via a plurality of sharp points to increase the sample size for sufficient testing volume and accuracy.

Art Unit: 3736

27. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in view of Griffith et al (WO 03/082091 A2). Anderson et al discloses the claimed invention except for the automated device of a construction sufficient to move a test strip into contact with the sample, automatically upon activation. Griffith et al teaches a device for obtaining and testing a sample comprising automatically, upon activation, dispensing and positioning a test strip for sample contact. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sample obtaining and testing device as taught by Anderson et al, with Griffith et al for the purpose providing a diagnosis and/or quantitative analysis while maintaining an analytical test strip in a non-contaminated form.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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